IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH DAKOTA
SOUTHERN DIVISION

PLANNED PARENTHOOD MINNESOTA, NORTH DAKOTA, SOUTH DAKOTA, and SARAH A. TRAXLER, M.D.,

Plaintiffs,

v.

KRISTI NOEM, Governor; JOAN ADAM, Interim Secretary of Health, Department of Health; and PHILIP MEYER, D.O., President, South Dakota Board of Medical and Osteopathic Examiners, in their official capacities,

Defendants.

Case No. 4:22-CV-04009-KES

REBUTTAL DECLARATION OF DANIEL A. GROSSMAN, M.D., F.A.C.O.G.

I, Daniel A. Grossman, M.D., F.A.C.O.G., declare and state as follows:

1. I am over 18 and competent to make this declaration.

2. I submit this declaration in support of Plaintiffs' Reply in Support of their Motion for a Preliminary Injunction. More specifically, this declaration responds to the opinions offered by Dr. Donna Harrison in support of Defendants' opposition to the Plaintiffs' motion.

3. The opinions in this declaration are based on my education, clinical training, experience as a practicing physician over the past twenty-seven years, my medical research, regular review of other medical research in my field, and attendance at professional conferences. My background is more extensively set forth in my opening declaration.[1] The facts in this declaration, unless otherwise stated, are based on my personal knowledge.

[1] Grossman Decl. ¶¶ 2–4 & Ex. A.

4. The vast majority of Dr. Harrison's opinions are about the overall safety of medication abortion, but she does not explain how these opinions pertain to the Rule that is being challenged in this case, which requires patients to make a third trip to their provider to receive misoprostol no sooner than 24 hours or later than 72 hours after they take the mifepristone. Because these opinions seem irrelevant to this case, I will start first with her opinions about the actual challenged requirement in this case, and then discuss why her overall opinions about the safety of medication abortion are unsupported.

Dr. Harrison Presents No Reasonable Justifications for the Rule

5. Dr. Harrison presents three reasons she believes the Rule is "reasonably related" to "patient safety," but none make medical sense. First, she suggests that because a very small percentage of patients "abort before taking misoprostol,"[2] all patients should be forced to return to their provider for an additional visit to confirm that they remain pregnant before taking the misoprostol. Citing no evidence, she further claims that taking misoprostol puts this small group of patients at risk of *C. sordellii* (Clostridium) infections.[3]

6. This is incorrect. There is no causal link between medication abortion and Clostridium infection.[4] Indeed, the U.S. Food and Drug Administration ("FDA") label for

[2] Dr. Harrison provides no reference for her assertion that 5% of patients abort after mifepristone alone; that figure is incorrect for patients beyond 49 days gestational age. At later gestational ages, the proportion of patients who abort after mifepristone and before misoprostol is lower (2% at 50–56 days, 0.8% at 57–63 days). The proportion overall is 2.8% (56 of 2,015). *See* Irving M. Spitz et al., *Early Pregnancy Termination with Mifepristone and Misoprostol in the United States*, 338 New Eng. J. Med. 1241, 1242–43 (1998).

[3] Harrison Decl. ¶¶ 31–32.

[4] *See* Am. Coll. Obstetricians & Gynecologists, *Practice Bulletin No. 225: Medication Abortion Up to 70 Days of Gestation*, 136 Obstetrics & Gynecology e31, e35 (Oct. 2020), https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation (hereinafter "ACOG Practice Bulletin").

Mifeprex states: "No causal relationship between the use of MIFEPREX and misoprostol and [fatal infections and bleeding] has been established."[5] The FDA clinical review team confirmed in 2016 that "[s]ince 2009, there have been no *C. sordellii* deaths associated with medical abortion in the U.S."[6]

7. Dr. Harrison also claims that a third visit to obtain misoprostol will allow a physician to determine if patients are experiencing complications, like hemorrhage.[7] As explained in more detail below, complications of medication abortion (including hemorrhage) are exceedingly rare. The FDA Mifeprex label states that serious adverse reactions—which include transfusion, infections, and hemorrhage—occur in less than 0.5% of women.[8]

8. If this were the rationale for the separate misoprostol visit, patients should come in every day after taking mifepristone, perhaps multiple times a day, to be seen by the provider. Rather than force patients to come in (potentially every day) to be evaluated prior to taking the misoprostol, it is the standard of care for providers to give patients information about potential side effects and a telephone number to call their clinician to discuss any concerns they may have, which their clinician can assess and determine how to triage, if necessary.

9. Dr. Harrison's final argument—that "the Rule will allow a physician to assess the patient's needs for pain control and before the misoprostol is administered"—makes even less

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[5] U.S. Food & Drug Admin. (FDA), Ctr. for Drug Evaluation & Rsrch., *Mifeprex (Mifepristone) Label 2016*, at 2 (2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf (hereinafter "Mifeprex Label").

[6] U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, *Application No. 020687Orig1s020*, at 83 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf (hereinafter "FDA Med. Rev.").

[7] Harrison Decl. ¶ 33.

[8] Mifeprex Label at 7–8.

sense.[9] I co-led a study about management of pain with medication abortion, which found that certain pain management regimens may prophylactically reduce pain if taken at the time of misoprostol.[10] The American College of Obstetricians and Gynecologists (ACOG) also recommends that "[p]atients should be sent home with appropriate instructions for analgesia with over-the-counter medications" (which I understand Plaintiffs do).[11] It is not clear to me why Dr. Harrison suggests that this conversation requires a separate in-clinic visit and should not be addressed at the visit when mifepristone is dispensed. Providers regularly, for a variety of medical indications and treatments, prescribe and dispense pain medications in advance and give patients instructions on when to take them and to call their provider if they need additional medication. In fact, providers regularly prescribe pain medication to their patients after a telephone consultation. I also understand that some of Planned Parenthood's patients live far away from the Sioux Falls health center. It is absurd to make patients travel long distances so that they can be assessed for pain. Dr. Harrison's proposal is also concerning because in instances where patients require prescription pain medications (instead of over-the-counter medications), requiring that these medications be prescribed at a separate visit could delay the patient's abortion or delay initiation of the pain-management medications. In addition, as Dr. Harrison notes, a very small proportion of patients will abort the pregnancy after taking mifepristone and before taking misoprostol; it is important that they know how to manage any pain they might experience and have analgesic medications on hand.

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[9] Harrison Decl. ¶ 34.

[10] Monica V. Dragoman, Daniel Grossman, et al., *Two Prophylactic Pain Management Regimens for Medical Abortion ≤63 Days' Gestation with Mifepristone and Misoprostol: A Multicenter, Randomized, Placebo-Controlled Trial,* 103 Contraception 163, 167 (2021).

[11] ACOG Practice Bulletin at e37.

10. To consider how unreasonable Dr. Harrison's opinions are, it is important to note that even when patients are being treated for early pregnancy loss (i.e., miscarriage management) and are prescribed the identical mifepristone-misoprostol regimen that medication abortion patients receive, or prescribed misoprostol alone, it is not the standard of care to require these patients to return to the health center to ensure that they have fully expelled the pregnancy tissue, or to be assessed for complications or pain before they are dispensed the medications. Often patients will learn that they have suffered a miscarriage at an appointment with their provider but they may not choose to begin a medication regimen to manage the miscarriage at that time. A patient can be counseled about their options and told to call their provider if they choose to start a regimen, or be told that if certain symptoms arise they can call their provider to have the medication prescribed. This is true despite the fact that these patients might be also experiencing pain or bleeding. In fact, heavy bleeding requiring transfusion appears to be more common with medical management of miscarriage compared with medication abortion.[12]

11. Oddly, Dr. Harrison spends numerous paragraphs arguing that medication abortion requires "at least two in-person meetings between the patient and a physician."[13] However, the two in-person meetings she is referring to are a first visit in which a patient receives a physical examination before the medication for a medication abortion is prescribed, and a second visit for a follow-up appointment after the patient has taken the mifepristone-misoprostol regimen. As such, Dr. Harrison seems to acknowledge that a separate visit for the dispensing of

[12] Courtney A. Schreiber et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378 New Eng. J. Med. 2161, 2169 tbl. 3 (2018); Justin J. Chu et al., Supplementary Appendix, *Mifepristone and Misoprostol Versus Misoprostol Alone for the Management of Missed Miscarriage (MifeMiso): A Randomised, Double-Blind, Placebo-Controlled Trial*, 396 Lancet 770, supplementary tbl. S5 (2020).

[13] Harrison Decl. ¶ 10.

misoprostol is not required. Moreover, Dr. Harrison's arguments about the need for these two visits—and the sorts of examinations she believes should be provided during them[14]—are entirely irrelevant to the Rule at issue here, which would require a third trip to the provider to obtain misoprostol, not an in-person examination.

12. I am not aware of any requirement in the Rule that patients be examined or receive confirmation of continuing pregnancy when they return to pick up their misoprostol.

13. I also disagree with Dr. Harrison's assertion that medication abortion requires an in-person follow-up appointment (after both the mifepristone and misoprostol have been taken).[15] Incredibly, Dr. Harrison cites both the FDA and ACOG for this proposition, when both organizations have confirmed that "[r]outine in-person follow-up is not necessary after uncomplicated medication abortion"[16] and that patients may instead confirm successful termination of pregnancy with an at-home pregnancy test or by visiting a more convenient provider for blood work.[17]

14. Thus, Dr. Harrison presents no reasonable argument for imposing on patients a separate in-person visit for the dispensing of misoprostol. As I explained in my initial declaration, the American Association of Pro-Life Obstetricians and Gynecologists (of which Dr. Harrison is Executive Director) submitted a citizen petition to the FDA in 2019 requesting several changes

[14] Harrison Decl. ¶¶ 10–13. Notably, neither the ACOG Practice Bulletin nor the FDA labeling for Mifeprex requires a physical exam to provide medication abortion. *See* Mifeprex Label; ACOG Practice Bulletin.

[15] Harrison Decl. ¶ 14.

[16] ACOG Practice Bulletin at e37.

[17] Mifeprex Label at 4 ("Termination can be confirmed by medical history, clinical examination, human Chorionic Gonadotropin (hCG) testing, or ultrasonographic scan.").

to the approval of mifepristone and misoprostol for medication abortion, including a request that the treatment "should require three office visits by the patient."[18] In December 2021, the FDA published a response to the citizen petition in which it reiterated its position that the evidence indicates that misoprostol may be safely self-administered at home. The FDA concluded: "Overall, studies support the efficacy of the mifepristone, in a regimen with misoprostol when taken by the patient at home, Therefore, we do not agree that an in-person visit is necessary to manage administration of misoprostol."[19]

Medication Abortion Is Safe

15. As I discussed in my previous affidavit, under any measure of safety, medication abortion is a safe medical treatment and a safe method of abortion. Numerous major, peer-reviewed studies—including several relied on by the FDA in approving an updated label for Mifeprex in 2016[20]—demonstrate the safe and effective use of mifepristone for medication abortion. As discussed in further detail below, Dr. Harrison's opinions about the safety of medication abortion are not supported by the medical literature.

16. Dr. Harrison's declaration selectively quotes data from the FDA's Mifepristone Adverse Events Summary ("Summary"), and, moreover, it fails to provide any context for the data.[21] The Summary reports adverse events over a period of 18 years, during which time

[18] Am. Assoc. of Pro-Life Obstetricians & Gynecologists & Am. Coll. of Pediatricians, *Citizen Petition*, at 7–10 (2019), available at https://www.regulations.gov/document/FDA-2019-P-1534-0001.

[19] FDA, Ctr. for Drug Evaluation & Rsrch., *Response Letter from FDA CDER to American Association of Pro-Life Obstetricians and Gynecologists and American College of Pediatricians,* at 18 (2021), available at https://www.regulations.gov/document/FDA-2019-P-1534-0016.

[20] Mifeprex Label at 7.

[21] *See* Harrison Decl. ¶ 25.

approximately 3.7 million women have received medication abortion using mifepristone for medical termination of pregnancy. Therefore, the hospitalization rate is 0.028% (1,042/3,700,000), the blood transfusion rate is 0.016% (599/3,700,000), and the infection rate is 0.011% (412/3,700,000).[22] These numbers are consistent with those reported in peer-reviewed studies.[23] However, Dr. Harrison omits this information from her declaration, even though it is included in the FDA's Summary.

17. Moreover, Dr. Harrison's declaration focuses on the 24 deaths linked to medication abortion reported in the Summary, but omits that 11 of those 24 deaths do not appear related to medication abortion.[24] Six of the deaths were related to drug use, overdose, or intoxication, two were homicides, one was a suspected homicide, one was due to suicide, and one resulted from emphysema.[25] That there are only 13 deaths cited in the Summary that are possibly related to the abortion,[26] out of 3.7 million patients, illustrates the extremely low mortality rate resulting from medication abortions.

18. Consistent with these low rates of adverse events, a large-scale study that reviewed the outcomes of 233,805 medication abortions performed in the United States found that only

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[22] FDA, RCM # 2007-525, *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/13/2018*, at 1–2 (2018), https://www.fda.gov/media/112118/download (hereinafter "FDA Post-Marketing").

[23] *See, e.g.*, Kelly Cleland et al., *Significant Adverse Events and Outcomes After Medical Abortion*, 121 Obstetrics & Gynecology 166, 169 (2013); Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstetrics & Gynecology 175, 175 (2015); Daniel Grossman & Kate Grindlay, *Safety of Medical Abortion Provided Through Telemedicine Compared With In Person*, 130 Obstetrics & Gynecology 778 (Oct. 2017).

[24] FDA Post-Marketing at 1.

[25] *Id*.

[26] As explained above, there is no causal link between medication abortion and Clostridium infection. *See supra* ¶ 6.

0.16% of patients experienced a significant adverse event (defined as hospital admission, blood transfusion, emergency department treatment, intravenous antibiotics administration, infection requiring treatment with intravenous antibiotics or admission to the hospital, or death).[27] My 2017 study of over 19,000 medication abortions in Iowa found that only 0.26% of patients experienced a clinically significant adverse event.[28] Another study that I co-authored in 2015 examined complications from approximately 55,000 abortions among California Medicaid patients and found a major complication rate of 0.31% for medication abortion patients.[29]

19. Dr. Harrison also incorrectly interprets information from the FDA Mifeprex label.[30] The label clearly states that ***serious adverse reactions***—which include transfusion, infections, and hemorrhage—occur in less than 0.5% of women.[31] However, Dr. Harrison groups the "***serious adverse reactions***" together with ***"adverse reactions***" to incorrectly imply that 85% of patients report serious adverse reactions.[32] The most common "adverse reactions," occurring in more than 15% of patients, are "nausea, weakness, fever/chills, vomiting, headache, diarrhea, and dizziness."[33] The label later describes these same reactions as "side effects."[34] While these side effects may be uncomfortable, they do not suggest that mifepristone is dangerous or unsafe.

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[27] Cleland et al., *supra* note 23, at 168–69.

[28] Grossman & Grindlay, *supra* note 23, at 780.

[29] Upadhyay et al., *supra* note 23, at 181.

[30] *See* Harrison Decl. ¶¶ 23–24.

[31] Mifeprex Label at 7–8.

[32] *See* Harrison Decl. ¶ 23 ("'About 85% of patients report at least one adverse reaction . . . .' These reactions include, but are not limited to, vomiting, headache, uterine hemorrhage, viral infections, and pelvic inflammatory disease." (quoting Mifeprex Label at 7–8)).

[33] Mifeprex Label at 7.

[34] *Id.* at 19.

Women who have decided to have a medication abortion are advised of these side effects and are instructed on how to address them.[35] They are given instructions on when to seek medical care, as with any prescription medication, and they are provided the contact information for their providers as an additional precaution.[36]

20. Dr. Harrison also mischaracterizes and omits key information when she excerpts text from the "black box warning" of the Mifeprex label.[37] Dr. Harrison quotes the label as stating: "Warning: Serious and Sometimes Fatal Infections or Bleeding."[38] However, she does not fully quote the label, which goes on to read: "Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical, and medical abortions, including following MIFEPREX use. No causal relationship between the use of MIFEPREX and misoprostol and these events has been established."[39] Omission of this key information gives the false impression that infections are more common and dangerous than they actually are, and it falsely insinuates that they are caused by Mifeprex—in direct contradiction to the language on the label.

21. Dr. Harrison also notes that Mifeprex has a Risk Evaluation and Mitigation Strategy ("REMS").[40] As I noted in my initial declaration, the FDA suspended the REMS requirement that mifepristone be dispensed at a clinic for the duration of the COVID-19

[35] *Id.* at 18 (listing these as possible symptoms after taking Mifeprex in the "Medication Guide," which is handed to patients).

[36] *Id.* at 16.

[37] *See* Harrison Decl. ¶ 24.

[38] *Id*.

[39] Mifeprex Label at 2.

[40] Harrison Decl. ¶ 24.

pandemic, and in December 2021 announced that it will permanently eliminate this provision of the REMS because it unnecessarily restricts access to care.[41]

22. In any event, the presence of a REMS does not contradict or undermine the well-established safety record of medication abortion. As outlined in my 2017 article, REMS "are intended for drugs that are known or suspected to cause serious adverse effects that cannot be mitigated simply by the label instructions," but "the Mifeprex elements do not meet these specifications. Mifepristone is not inherently toxic or harmful to the woman using it."[42] Notably, other countries such as Australia and Canada have not imposed safety regulations analogous to the REMS, and they have not encountered substantial safety concerns when administering mifepristone.[43] The two serious risks described on the Mifeprex label are also not unique to the drug. They occur after many other common obstetrical and gynecological procedures that are not subject to the same regulations as medication abortion.[44] The "rationale for singling out Mifeprex as needing such measures to ensure safety is lacking, and the Mifeprex elements can hardly be justified as 'commensurate' with the risks"—as the safety information included on the FDA-approved Mifeprex label itself makes clear. [45]

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[41] *See* FDA, Questions and Answers on Mifeprex (2021), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex.

[42] Mifeprex REMS Study Group, *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, 376 New Eng. J. Med. 790, 790–793 (2017).

[43] *Id.* at 792; *see also* Laura Schummers et al., *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada*, 386 New Eng. J. Med. 57 (2022).

[44] Mifeprex REMS Study Group, *supra* note 42, at 792.

[45] *Id*.

23. Dr. Harrison incorrectly asserts that medication abortions are more dangerous than surgical abortions.[46] Medication abortions have an extremely low complication rate relative to other medical procedures, including surgical abortion. While it is true that the "failure rate" for medication abortion, *i.e.*, the proportion of women who require a vacuum aspiration to complete the abortion, is higher than the proportion of women who undergo a surgical abortion and require a repeat procedure, this does not make medication abortion more risky. In fact, it is a known feature of the method that is clearly explained to patients during the counseling process.

24. Dr. Harrison also implies that medication abortions at later gestational ages are more dangerous than those at earlier gestational ages because they fail at higher rates.[47] But again, the "failure rate" of medication abortions at various gestational ages is irrelevant to the safety of the procedure.

25. Further, as is the case in all other medical contexts, it should be up to the patient, in consultation with her medical provider, to weigh the risks and benefits of medication versus surgical abortion. As I discussed in my previous affidavit, medication abortion has certain notable advantages over surgical abortion (*e.g.*, it affords greater flexibility with respect to timing, avoids the use of anesthesia or sedation, and is less invasive and more private), and it is medically preferable for those with certain medical or anatomical conditions.[48] Moreover, the relative risk of surgical abortion is not at all relevant to the question of whether patients must make a third trip to a provider to obtain misoprostol.

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[46] *See* Harrison Decl. ¶¶ 15–18, 22.

[47] *See id.* ¶¶ 20–21.

[48] *See* Grossman Decl. ¶¶ 26–30.

Dr. Harrison Misrepresents the Medical Literature on the Safety of Medication Abortion

26. Dr. Harrison misconstrues data from the FDA and major peer-reviewed studies, and instead relies upon outdated and unreliable studies to support her opinions. Dr. Harrison asserts that the FDA fails to adequately monitor complications.[49] She relies on a study she co-authored that reviewed FDA Adverse Event Reports from 2000 through 2004.[50] These data are from the first four years Mifeprex was used for medication abortion in the United States and are over 15 years old. Her study implies that the adverse event rate is underreported, but that assertion is speculative. Dr. Harrison fails to acknowledge the subsequent robust review of adverse events based not only on FDA reports, but also U.S. clinical studies published in peer-reviewed journals. Neither her article nor her declaration support the conclusion that complications are unknown or widely underreported.

27. The FDA carefully monitors reports of complications, and the agency's data are as complete for mifepristone as they are for any other FDA-approved drug. Nearly two decades of post-market experience and clinical studies have confirmed that medication abortion is safe and effective.[51]

28. Specifically, the FDA's recent review of 15 years of post-market experience and updated clinical studies highlights the overall safety and efficacy of medication abortion.[52] The

[49] Harrison Decl. ¶¶ 26–27.

[50] Margaret M. Gary & Donna J. Harrison, *Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient*, 40 Annals of Pharmacotheraphy 191, 191 (2006).

[51] *See* Regina Kulier et al., *Medical Methods for First Trimester Abortion*, Cochrane Database of Systemic Revs. (Nov. 2011).

[52] *See* FDA Med. Rev. at 47–76; *see also* U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., *Application No. 020687Orig1s020*, 10–12 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020SumR.pdf [hereinafter "FDA

FDA's efficacy review in connection with proposed changes to the Mifeprex label evaluated the quality of the studies that supported the current label, including whether the literature was an adequate primary information source to support the FDA's conclusion that the current medication abortion protocol is safe. Moreover, the FDA's medical review provides detailed information regarding the medical literature reviewed by the FDA and its reasons for approving the label update. The 14 major studies and literature reviews relied upon by the FDA in approving the updated label are listed at Table 1 of the FDA's Medical Review.[53] The FDA's clinical review team identified key serious adverse events—including hospitalization, serious infection, bleeding requiring transfusion, and ectopic pregnancy—discussed in the medical literature.[54] The FDA team noted that hospitalization rates associated with medication abortion ranged from 0.04% to 0.6% (in a population of over 14,000 women); serious infection occurred in 0% to 0.2% of cases (in a population of over 12,000 women); and rates of transfusion were 0.03% to 0.5% (in a population of over 17,000 women).[55] These rates of adverse events are well within the range of an acceptable level of risk for a medical treatment.[56] The FDA noted that the regimen "has been studied extensively in the literature using U.S. and global sites" [57] and concluded that major adverse events were "exceedingly rare."[58]

Summary Rev."].

[53] *See* FDA Med. Rev. at 18, Table 1; *see also* FDA Med. Rev. at 91–98, App. 9.5, for the full list of references reviewed by the FDA.

[54] FDA Summary Rev. at 10.

[55] *Id.* at 10–11.

[56] FDA Med. Rev. at 47.

[57] FDA Summary Rev. at 11.

[58] FDA Med. Rev. at 47.

29. Dr. Harrison is also wrong to suggest that medication abortion complications are undercounted because patients may conceal the fact of their abortion from the ER.[59] The 2015 Upadhyay study, which I co-authored, analyzed complication rates resulting from abortions in more than 50,000 California Medicaid patients.[60] The study reviewed billing codes to evaluate the type of medical care patients received following an abortion, both at the location where they received the abortion and at other locations, including the emergency department. Because the study's methodology captured all care women received post-abortion, it is one of the most thorough and reliable studies on abortion complication.

30. The Upadhyay study found that only 3.1 out of 1,000 patients (0.31%) in this study experienced a major complication (hospital admissions, surgery, or blood transfusion) following a medication abortion.[61] By contrast, nearly 3% (i.e., ten times higher than for medication abortions) of all women who give birth vaginally have a prolonged hospital admission or early re-admission to the hospital. For cesarean delivery (a major operation that more than 30% of American women who give birth will undergo), the figure is three times higher.[62]

31. Dr. Harrison also ignores that the study employed an extremely broad definition of "complications." The study "defined a complication as any postabortion adverse event that received an abortion-related diagnosis or treatment at any source of care, including EDs [emergency departments] and the original abortion facility within 6 weeks of an abortion

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[59] *See* Harrison Decl. ¶ 28.

[60] Upadhyay et al., *supra* note 23.

[61] *Id*. at 175.

[62] Patricia R. Hebert et al., *Serious Maternal Morbidity After Childbirth: Prolonged Hospital Stays and Readmissions*, 94 Obstetrics & Gynecology 942, 944 (1999); Brady E. Hamilton, Joyce A. Martin & Stephanie J. Ventura., *Births: Preliminary Data for 2011*, 61 Nat'l Vital Stat. Rep. 1, 2 (2012).

procedure."[63] Even following that broad definition of "complication," the study reported only a 5.2% rate of complications for medication abortions.[64] The study also posits multiple reasons why it may have *over-reported* complications.[65]

32. The studies Dr. Harrison relies on to assert that "[m]edication abortions commonly lead to complications" are inferior to the studies relied upon by the FDA and by Plaintiffs.[66] Both the Mulligan study[67] and the Niinimäki study[68] have serious methodological limitations. The Mulligan study has a small sample size[69] and does not control for the route of misoprostol administration or timing of misoprostol administration.[70] The Niinimäki study does not differentiate between different medication abortion protocols.[71] The Niinimäki study also does not define how hemorrhage was quantified.[72] And in any event, the Mulligan study concludes that "[t]he rate of any adverse outcome following early abortion is low" and that "little can be made of the likelihood of the most serious adverse outcomes of early abortion except to note that

[63] Upadhyay et al., *supra* note 23, at 179.

[64] *Id.* at 181.

[65] *See id.* at 182.

[66] Harrison Decl. ¶¶ 15–18.

[67] Ea Mulligan & Haley Messenger, *Mifepristone in South Australia: The First 1343 Tablets*, 40 Austl. Fam. Physician 342 (2011).

[68] Maarit Niinimäki et al., *Immediate Complications After Medical Compared with Surgical Termination of Pregnancy*, 114 Obstetrics & Gynecology 795 (2009).

[69] Mulligan & Messenger, *supra* note 67, at 343 (947 medication abortion in the sample compared to 233,805 medication abortions in the sample in Cleland et al., *supra* note 23, and 11,319 medication abortion in the sample in Upadhyay et al., *supra* note 23).

[70] *Id*.

[71] Niinimäki et al., *supra* note 68, at 796.

[72] *Id.* at 799–800.

they are rare."[73] The Niinimäki study finds that there is a "low level of serious complications"[74] and medical and surgical abortion are "generally safe."[75]

Conclusion

33. The Rule presents arbitrary, burdensome, and unreasonable restrictions on the provision of medication abortion that serve no medical purpose in light of the safety of that treatment.

34. Dr. Harrison presents no evidence-based arguments in support of requiring an in-person visit for misoprostol. She also misrepresents existing studies and relies on outdated or debunked information to suggest that medication abortion is dangerous, when—in fact—the data, research, and credible peer-reviewed studies show it is extremely safe.

35. It is my opinion that the Rule burdens women's access to medication abortion for no medically justifiable reason.

[73] Mulligan & Messenger, *supra* note 67, at 343–44.

[74] Niinimäki et al., *supra* note 68, at 803.

[75] *Id.* at 798.

Pursuant to 28 U.S.C. § 1746, I certify under penalty of perjury that the foregoing is true and correct.

Executed on: February 3, 2022

Daniel A. Grossman, M.D., F.A.C.O.G.